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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,310	11/13/2001	Elias Georges	112418.122	5815
23483	7590	12/08/2004	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP			GABEL, GAILENE	
60 STATE STREET			ART UNIT	PAPER NUMBER
BOSTON, MA 02109			1641	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/010,310

Applicant(s)

GEORGES, ELIAS

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 10-74 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - ii. Claims 10-20, 22, and 23, drawn to method of identifying polypeptide having specificity for binding a peptide in human P- glycoprotein 1, classified in class 436, subclass 523, for example.
  - iii. Claims 10-19 and 22-24, drawn to method of identifying polypeptide having specificity for binding a peptide in human P- glycoprotein 3, classified in class 436, subclass 523, for example.
- IIi. Claims 26-36, 38, and 39, drawn to method of identifying peptide in human P- glycoprotein 1 which binds a polypeptide, classified in class 435, subclass 7.92, for example.
- IIii. Claims 26-35 and 38-40, drawn to method of identifying peptide in human P- glycoprotein 3 which binds a polypeptide, classified in class 435, subclass 7.92, for example.
- IIli. Claims 42-52, 54, and 55, drawn to identifying a compound that modulates binding between polypeptide and a peptide in human P- glycoprotein 1, classified in class 436, subclass 34, for example.

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- IIIii. Claims 42-51 and 54-56, drawn to identifying a compound that modulates binding between polypeptide and a peptide in human P- glycoprotein 3, classified in class 436, subclass 34, for example.
- IVi. Claims 58-69 and 71, drawn to support having peptide from human P- glycoprotein 1, classified in class 435, subclass 287.2, for example.
- IVii. Claims 58-68, 71, and 72, drawn to support having peptide from human P- glycoprotein 3, classified in class 435, subclass 287.2, for example.
- V. Claim 74, drawn to method of purifying tubulin, classified in class 530, subclass 305, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, Invention I has separate utility such as use in platelet surface protein binding and coagulation studies. See MPEP § 806.05(d).

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different

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functions, and different effects in that the set of peptides in Invention I are combined with a polypeptide to identify specificity therebetween and in Invention III, the set of peptides are combined with a polypeptide in the presence of a test compound to determine its modulatory effect upon their binding interaction.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the support can be used for affinity chromatography to capture and isolate selected protein.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects in that the set of peptides in Invention I are combined with a polypeptide to identify specificity therebetween and in Invention V, a sample containing tubulin is contacted with support having attached thereto, a first peptide and a second peptide that bind tubulin, then eluted in order to obtain purified tubulin.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation and different

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functions in that the set of peptides in Invention II are combined with a polypeptide to identify specificity therebetween and in Invention III, the set of peptides are combined with a polypeptide in the presence of a test compound to determine its modulatory effect upon their interaction.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the support can be used in laser trapping method for capturing specific selected protein.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions in the set of peptides in Invention II are combined with a polypeptide to identify specificity therebetween, and in Invention V, a sample containing tubulin is contacted with support having attached thereto, a first peptide and a second peptide that bind tubulin, then eluted in order to obtain purified tubulin.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case, modulation of interaction between a set of overlapping peptides and a protein can be effected using physical stimulus, i.e. temperature.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions in that the set of peptides in Invention III, the set of peptides are combined with a polypeptide in the presence of a test compound to determine its modulatory effect upon their interaction and in Invention V, a sample containing tubulin is contacted with support having attached thereto, a first peptide and a second peptide that bind tubulin, then eluted in order to obtain purified tubulin.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the support can be used with gel microdrop technology to isolate specific soluble protein.

Further, human P-glycoprotein 1 and human P-glycoprotein 3 in claims 20, 24, 36, 40, 52, 56, 69, and 72 in each of inventions (Ii and Iii), (Iii and Iii), (Iiii and Iiii), (Ivi and Ivi) and (Ivi and Ivi), respectively, are drawn to patentably distinct inventions, as distinct proteins bearing peptides comprising materially different amino acid sequences

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as evidenced by separate SEQ ID Numbers. These separate peptides bear distinct structural or biochemical properties and have distinct binding epitopes. Therefore, each disclosed patentably distinct peptide is considered a separate invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because the search required for each one of Group I, II, III, IV, and V having either one of human P-glycoprotein I or human P-glycoprotein 3, is not required for the other of Group I, II, III, IV, and V having either one of human P-glycoprotein I or human P-glycoprotein 3, restriction for examination purposes as indicated is proper. Literature search for each method and product is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

2. This application contains claims 21, 25, 37, 41, 53, 57, 70, and 73 are directed to the following patentably distinct species of the claimed invention:

- a) human P-glycoprotein I
  - species: SEQ ID NO. 1 domain
  - SEQ ID NO. 2 domain
  - SEQ ID NO. 3 domain
- b) human P-glycoprotein 3
  - species: SEQ ID NO. 4 domain

SEQ ID NO. 5 domain

SEQ ID NO. 6 domain

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species and subspecies for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 10-20, 22-24, 26-36, 38-40, 42-52, 54-56, 58-69, 71, 72, and 74 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35

U.S.C. 103(a) of the other invention.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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November 15, 2004

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